

October 15, 2001

Mutual Pharmaceutical Company  
Attention: Robert Dettery  
1100 Orthodox Street  
Philadelphia, PA 19124

Dear Sir:

This is in reference to your abbreviated new drug application dated November 24, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Sotalol Hydrochloride Tablets, 80 mg, 120 mg, 160 mg, 240 mg.

Reference is also made to your amendments dated February 1 and April 19, 1999; and April 23, and September 10, 2001.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Sotalol Hydrochloride Tablets, 80 mg, 120 mg, 160 mg, 240 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Betapace<sup>®</sup> Tablets 80 mg, 120 mg, 160 mg, and 240 mg, respectively, of Berlex Laboratories Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

cc: ANDA 75-515  
Division File  
Field Copy  
HFD-610/Wm. Rickman (Acting)  
HFD-330  
HFD-205  
HFD-92

Endorsements:

HFD-646/B.Mirzai-Azarm/09/26/01  
HFD-647/U.Venkataram/09/27/01;10/05/01  
HFD-617/S.Shepperson/10/10/01  
HFD-613/A.Vezza/10/11/01  
HFD-613/C.Hoppes/10/11/01

v:\firmsam\mutual\ltrs&rev\75515apdf  
F/T by: alm/10/10/01

APPROVAL